

serum albumin (2 points) as independent risk factors that predict 1 year mortality in elderly patients. The index did not include age as a risk factor however the mean age of the 1495 patients used to develop the index was 81. In the derivation cohort of the Walter Index the 1 year mortality was 13% in the lowest-risk group (0-1 point), 20% in the group with 2 or 3 points, 37% in the group with 4 to 6 points, and 68% in the highest-risk group (>6 points).

Results: The mean age was 81±7. The mean logistic Euroscore was 18.1±14.3%. The mortality at 30 days was 0% (n=0) and the 6 month mortality was 3.1% (n=1), while the 12 month mortality was 12.5% (n=4). When the index was applied to the TAVI patients there were n=4 with 0-1 point, n=22 with 2 to 3 points and n=6 with 4 to 6 points with predicted 1 year mortalities of 13%, 20% and 37% respectively.

Conclusion: Mortality after TAVI compares favourably with that predicted for age and comorbidity by a validated 1 year prognostic index. These indexes are important to help keep perspective on what may be the best achievable outcomes in the current population eligible for TAVI.

TCT-501

Transcatheter Aortic Valve Implantation: Procedural Time, Contrast Dye Amount and Radiation Exposure According to Different Approaches.

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Background: Transcatheter aortic valve implantation (TAVI) is an emergent alternative technique to surgery in high-risk patients with aortic stenosis. Two different prostheses are available for clinical use (CoreValve System, Medtronic, Minneapolis, MN, USA and Edwards Sapien valve, Edwards Lifesciences, Irvine, CA, USA), that can be implanted through 3 different approaches: transfemoral (TF), transsubclavian (TS) and transapical (TA). Aim of this study is to analyze differences among the different approaches in terms of procedural time, contrast dye amount and radiation exposure time and dose.

Methods: Between June 2007 and April 2010, 128 pts underwent TAVI at our institution. CoreValve prosthesis (18Fr sheath) was implanted by totally percutaneous TF approach (pTF) or by surgical cut-down of left subclavian artery (TS). Edwards Sapien valve was implanted after surgical cut-down of femoral artery (sTF, 22-24Fr), by pTF approach (18-19Fr) or by TA approach (26Fr). Procedural time was measured as "skin to skin" in all cases.

Results: Out of 128 patients, 87 underwent CoreValve implantation (82 pTF, 5 TS) and 41 Edwards Sapien implantation (1 pTF, 10 sTF, 30 TA). Procedural success was 94.5%. Procedural time, radiation time and dose and contrast dye amount according to different approaches are detailed in table below. There were significant differences among groups in terms of procedural duration and exposure dose. Post hoc analysis allowed to identify that both sTF and TA approaches were significantly longer than pTF. On the other side, TA approach was characterized by lower exposure dose than pTF.

Variable	pTF (83 pts)	sTF (10 pts)	TS (5 pts)	TA (30 pts)	p
Procedural length (min)	71.5±35.2*	112.9±29.9*	111.4±36.1	111.8±39.1*	<0.0001
Exposure time (min)	23.1±9.9	20.4±5.8	31.0±3.4	17.7±14.1	0.05
Exposure dose (Gy/cmq)	154.1±99.4*	124.9±60.6	187.0±84.9	88.8±48.7*	0.02
Dye amount (ml)	186.2±85.0	204.6±76.7	182.2±104.1	164.0±61.2	0.48

Conclusion: Totally percutaneous transfemoral approach is the fastest procedure for TAVI. However this approach seems to require an higher dose of X-rays than the TA one.

*and * pair the groups with a significative statistical difference at post hoc analysis

TCT-502

Permanent Pacemaker Requirement after Transcatheter Aortic Valve Implantation

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Background: Complete atrioventricular block is a well-known complication after transcatheter aortic valve implantation (TAVI). In the current literature, a permanent pacemaker (PM) implantation rate in the range of 19 to 35% is reported after TAVI with the self-expanding CoreValve bioprosthesis. After 100 revalving procedures we analyzed our own patient series regarding need for permanent PM implantation.

Patients and Methods: Between May 2007 and February 2010, 100 patients (35 male, 65 female; mean age 80 ± 6 years) with symptomatic severe aortic stenosis and a logistic EuroSCORE >20% underwent a TAVI. A temporary PM was installed in all patients for rapid pacing during valvuloplasty and for ventricular back-up pacing in case of bradycardia. After balloon valvuloplasty, the self-expanding CoreValve prosthesis (diameter 26 mm, n = 51; 29 mm, n = 49) was implanted using the current 18 French delivery catheter system. Postprocedurally all patients were transferred to the intermediate care unit for a 48-hour monitoring period. Only patients with symptomatic bradycardia were scheduled for permanent PM implantation according to the current guidelines.

Results: Acute procedural success rate was 99%. TAVI resulted in a significant reduction of peak and mean aortic transvalvular pressure gradients and a significant increase of calculated aortic valve area. 13 of 100 patients already had a permanent PM implantation prior to selection for TAVI and were therefore excluded from analysis. In seven of the remaining 87 patients (8.0%; 4 male, 3 female; mean age 79 ± 5 years) a permanent PM was implanted two to seven days after TAVI due to symptomatic bradycardia. In five of these seven patients a 29 mm CoreValve prosthesis was implanted, one patient was revalved with a 26 mm prosthesis, and in one patient the prosthesis could not be safely positioned and had to be removed before complete deployment.

Conclusion: The percentage of new permanent PM implantation in our TAVI series is much lower than previously reported in the literature (8% vs. 19 - 35%). Reasons for that might be that we did not implant any PM on a prophylactic basis (i.e. new-onset left bundle branch block or asymptomatic bradycardia) or for administrative logistical purposes (i.e. to promote earlier discharge from intermediate care unit or hospital). Furthermore, we aimed at a more superior positioning of the CoreValve prosthesis within the left ventricular outflow tract to mitigate conduction abnormalities and to reduce the need for permanent PM implantation. Finally, also prosthesis size could matter.

TCT-503

Vascular Access Site Complications after Transarterial Aortic Valve Implantation: Impact on 30day Mortality

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Older patients (pts) with symptomatic aortic valve stenosis who have comorbidities are more frequently treated by transcatheter aortic valve implantation (TAVI). The transarterial approaches (femoral, axillary/subclavian artery) do not require deep sedation or mechanical ventilation. However, access site complications might bear the risk of access mortality. Aim of the present analysis was to elucidate the impact of access site complications on short term outcome after TAVI.

Methods: Pts with significant aortic stenosis who were treated transarterially with the Medtronic CoreValve ReValving System were analyzed. Vascular access site complications were defined as vessel dissection, perforation, occlusion, and malfunction of the closure device requiring surgery, respectively. These data and 30day-mortality were collected prospectively.

Results: Since 2006, a total of 371 pts (age 81±6 years; Logistic EuroSCORE 23.9±14.1%) were treated with the Medtronic CoreValve ReValving System. The size of the delivery system was 21F in the first 14 patients, and 18 F in the remaining cohort. In seven patients, the axillary/subclavian artery was used as the access site, all other patients were treated transfemorally.

There was one intraprocedural death (0.27%) and the over all 30 day mortality was 11.6%. A total of 53 pts (14.3%) had an access site complication requiring stent implantation or surgical closure. Of these patients, 17 (4.6%) received a stent due to vessel dissection, 10 (2.7%) had vessel perforation requiring placement of a covered stent, and in 26 patients (7.0%) surgical closure of the access site was necessary, respectively. Patients with access site complications had a more than 50% higher 30-day-mortality as compared to those without vascular complications (20.8% vs. 9.9% (p <0.02)). A peripheral artery occlusive disease or BMI were not associated with a higher risk of access site injury.

Conclusion: TAVI represents an alternative to conventional aortic valve surgery in older patients with comorbidities. However, the occurrence of access site complications is associated with a higher mortality. Therefore, careful preinterventional access site screening and immediate management of vascular complications are important strategies to minimize the risk of mortality and morbidity after TAVI.

Valvular Heart Disease - Mitral

(Abstract Nos 504-510)

TCT-504

Approach to Treat Mitral Regurgitation: Human Data and Final Percutaneous Prototype

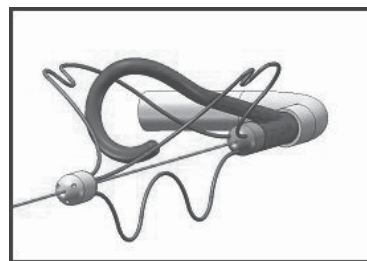
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Background: The QuantumCor™ device uses radiofrequency (RF) energy at sub-ablative temperatures to produce contraction of the mitral valve annulus to reduce mitral regurgitation (MR).

Methods: Sixteen healthy sheep had RF energy applied for a mean of 60 seconds at sub-ablative temperatures to replicate mitral annular ring in a cardiopulmonary bypass model. In a separate study, linear segments of mitral annulus of porcine (in situ), human (in situ) and sheep (in vivo) were treated with RF heat at 65°C, 50W for 60 seconds. In the porcine and human model, the segments were measured pre and post treatment with a pair of calipers. In the in vivo sheep measurements were performed by intracardiac echo (ICE) pre and post treatment.

Results: In the chronic animal series, the mean anterior-posterior (AP) annular distance was reduced by a mean of 5.75 ± mm (23.8% reduction) (p<0.001). In the cross species study, the P value based on the t-test for ovine values was 0.05. We have evaluated the utility of energy to replicate in a fluid filled system the same results obtained in our blood free cardiopulmonary bypass sheep. We also introduced the percutaneous catheter (Figure 1).



Conclusion: The response to human tissue appears promising and may be an approach to treat patients with mitral regurgitation percutaneously.